

SEP - 9 1997

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510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared: July 17, 1997

Submitter: Bayer Corporation, Business Group Diagnostics

Address: 1884 Miles Avenue, P.O. Box 70
Elkhart, IN 46515
(219) 262-6929

Contact: Rosanne M. Savol, R.A.C.
Manager, Regulatory Affairs

Device: Trade/Proprietary Name: CLINITEK® Microalbumin Reagent Strips
Common/Usual Name: Test for microalbumin in urine
Test for creatinine in urine
Document Control Number: K97 _____

Classification: Division of Clinical Laboratory Devices
Panel - Clinical Chemistry and Toxicology
Classification Code - 75 JIR (Urinary Protein or Albumin)
75 CGX (Alkaline Picrate, Colorimetry,
Creatinine)

Predicate Devices: Micral-Test® strips (Boehringer Mannheim Corporation); Microalbumin Assay/Array® Analyzer (Beckman Instruments Inc.); SPQII™ Reagent (INCSTAR Corp.)/Roche COBAS-FARA® II Analyzer/Ciba-Corning Express Plus; Microprotein Reagent (Sigma Diagnostics)/Roche COBAS MIRA Analyzer/Paramax® Analytical System/DuPont XL System; Quantimetrix BGR Total Protein (Quantimetrix)/TECHNICON RA® 1000 Random Access Analyzer; CX3 Creatinine Reagent (Beckman)/ Beckman CX3 SYNCHRON® Analyzer; Paramax® Creatinine Reagent (Dade Diagnostics)/Paramax Analytical System; Miles Creatinine Reagent (Bayer)/TECHNICON RA 1000 Random Access Analyzer; Dade® Creatinine Reagent/DuPont XL System; DCA 2000+ Microalbumin/Creatinine Assay (Bayer)

Device Description:

CLINITEK® Microalbumin Reagent Strips are firm plastic strips that contain two reagent areas to test for microalbumin (low concentration of albumin) and creatinine in urine. CLINITEK Microalbumin Reagent Strips are dipped into a urine specimen and “read” instrumentally by the CLINITEK® 50 or CLINITEK® 100 Urine Chemistry Analyzer. In addition to providing an albumin and a creatinine result, an albumin-to-creatinine ratio is also determined. Semi-quantitative results are available within one minute.

Intended Use:

CLINITEK® Microalbumin Reagent Strips are for screening urine specimens for microalbuminuria as an aid in the detection of patients at risk for developing kidney damage. CLINITEK Microalbumin Reagent Strips are for professional use in point-of-care testing locations such as physician office laboratories, clinics, and hospitals.

Technological Characteristics:

The CLINITEK® Microalbumin assay is a dip-and-read reagent strip allowing detection of urinary albumin at 20 to 40 mg/L, and the albumin-to-creatinine ratio of 30 to 300 mg/g. The albumin test is based on dye binding using a high affinity sulfonephthalein dye. At a constant pH, the development of a blue color is due to the presence of albumin. The creatinine test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The color of the reagent areas are read by the CLINITEK® 50 and CLINITEK® 100 instrument at specified times and the results are displayed or printed in clinically meaningful units.

Assessment of Performance:

The performance of CLINITEK® Microalbumin Reagent Strips was studied in clinical settings by typical users of the system and results compared to currently used tests for microalbumin and creatinine in urine. The studies demonstrated that typical users in decentralized, point-of-care laboratories can obtain clinical test results that are substantially equivalent to current methods.

Conclusion:

CLINITEK® Microalbumin Reagent Strips for use with the CLINITEK® 50 and CLINITEK® 100 Urine Chemistry Analyzers provide a convenient method for screening for microalbumin and creatinine in urine. Studies show that the system can be used in decentralized and point-of-care laboratories and provide clinical results comparable to other test methods in current clinical laboratory practice.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP - 9 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Rosanne M. Savol, R.A.C.
Manager, Regulatory Affairs
Bayer Corporation
1884 Miles Avenue
P.O. Box 70
Elkhart, Indiana 46514-0070

Re: K972706
CLINITEK® Microalbumin Reagent Strips
Regulatory Class: II
Product Code: CJG, JFY
Dated: July 17, 1997
Received: July 21, 1997

Dear Ms. Savol:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

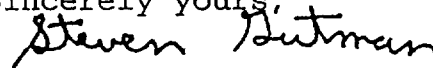
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

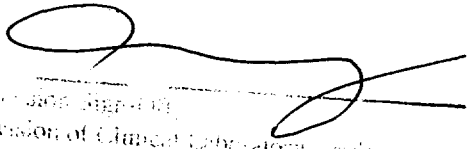
510(k) Number (if known): _____

Device Name: CLINITEK® Microalbumin Reagent Strips

Indications for Use: CLINITEK Microalbumin Reagent Strips are firm plastic strips that contain two reagent areas to test for small amounts of albumin in urine (microalbuminuria), creatinine in urine, and also determine the albumin-to-creatinine ratio in urine. The strips are read instrumentally using the CLINITEK® 50 or CLINITEK® 100 Urine Chemistry Analyzer and provide semi-quantitative results. CLINITEK Microalbumin Reagent Strips can be used for screening urine specimens for microalbuminuria as an aid in the detection of patients at risk for developing kidney damage. CLINITEK Microalbumin Reagent Strips are for professional use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Clinical Laboratory Devices
510(k) Number 62972726

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)